IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	S. Bailey, et al.	Attorney Docket:	6006-009
Serial No.:	09/783,633	Examiner:	C. Miller
Filed:	February 14, 2001	Art Unit:	3738
Title:	IN VIVO SENSOR AND METHOD OF MAKING SAME	Customer No.:	29,335

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APPELLANT'S REPLY BRIEF ON APPEAL

This Reply Brief is being filed in response to the Examiner's Answer (hereinafter referred to as "Examiner's Answer") mailed on April 12, 2007.

1. Status of Claims

Claims 1-47, 50, and 67 have been cancelled. Claims 48-49 and 51-66 stand rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 759 730 B1 to Burmeister et al. (hereinafter referred to as "Burmeister"). The rejection of claims 48-49 and 51-66 is under appeal.

2. Grounds of Rejection to be Reviewed on Appeal

Whether claims 48-49 and 51-66 are unpatentable under 35 U.S.C. § 102(b) over Burmeister.

3. Argument

Rejection of claims 48-49 and 51-66 under 35 U.S.C. § 102(b) over Burmeister

In the Examiner's Answer, the Examiner maintains the rejection of claims 48-49 and 51-66 under 35 U.S.C. §102(b) on grounds that claims 48-49 and 51-56 are purportedly anticipated by Burmeister. Applicant submits that Burmeister fails to disclose each and every element of claims 48-49 and 51-66. Applicant further submits that Burmeister fails to enable one of ordinary skill in the art to make and use the invention in a manner that anticipates the claimed invention. Accordingly, Applicant submits that the Examiner's anticipation rejection is improper and respectfully requests reconsideration of the present application.

A. Burmeister fails to teach a sensor element that is a distinct element from the structural elements, as recited in claim 48.

Claim 48 recites:

> 48. An implantable sensor device having a plurality of structural elements capable of expanding within an anatomical passageway comprising first and second structural elements where at least some of the plurality of first structural elements **further comprise** at least one first sensor element and where at least some of the plurality of second structural elements **further comprise** at least one second sensor element, both sensors which selectively detect an energy stimulus and responds to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member. [Emphasis added.]

In short, claim 48 recites, *inter alia*, the following four distinct elements: a first structural element, a first sensor element, a second structural element, and a second sensor element.

On page 5, lines 1-10 of the Examiner's Answer, the Examiner argues:

> First, applicant has not claimed that the sensor element need be a distinct element different from the structural elements. Distinct elements are not required by the claims. Further, applicant's elected embodiment, shown in figures 5-7B does not show the sensor to be distinct structures from the structural elements, therefore, not even the applicant has support for such distinct structures. Applicant's stent device seen in figures 5-7B is a stent having structural members (struts of the stent), wherein an area of the stent has sensing capabilities do [sic] to the material composition thus has been termed a "sensing element". Burmeisters's stent having struts (structural elements) that are responsive (thus inherently acting as a sensor) is configured exactly the same as the applicants [sic], thus has "sensor elements" just as much as the applicant's device does.

Applicant respectfully disagrees. Contrary to the Examiner's assertions, Applicant has claimed that the sensor elements are distinct elements distinguished from the structural elements. As recited above, the pending claims positively recite that the stent structure is comprised of at least two groups of structural elements, each group containing a sensor element distinct from that of the other group. Thus, the sensor elements combined do not form the entire stent structure itself. As widely known by those skilled in the art, the term "further comprise", as applied in the framework of currently written claim 48, clearly indicates that the recited sensor elements are entities that are distinct from the recited structural elements. In other words, the structural elements and the sensor elements of the claimed invention are considered as individual elements. Thus, unlike what is described in Burmeister, the sensor elements of the claimed invention do not form the entire stent structure itself. Burmeister does not teach, either expressly or implicitly, a sensor device in which at least two groups of structural elements have their own distinctive sensor element, as is presently claimed.

Applicant's construal of the claim language for claim 48 to require distinction between structural elements and sensor elements is corroborated and supported by the originally filed application on page 22, lines 6-12, wherein Applicant discloses:

> In order to provide sensor functionality and permit vascular imaging and modeling, the inventive sensor 30 further comprises regions of the structural elements 32, 36 which have a **second shape memory and/or superelastic material** therewith (hereinafter the "second material"), which has, for example, a martensite transition temperature (or σ coefficient) which is higher than that of the

> base material for the structural elements 32, 36. Having a second material with either a higher transition temperature or a higher σ coefficient, allows for changing device 30 geometry or conformation upon application of internally or externally applied forces.

Similarly, on page 23, lines 22-26 of the originally filed application, Applicant further discloses that the structural elements (*i.e.*, wall elements 32, 36) are distinct from the sensor elements:

> Alternatively, **portions** of the wall elements 32, 36 may be fabricated of a **first material** having a transition point T_1, while **other portions** of the wall elements 32, 36 … are fabricated of **second material** having a transition point T_2. [Emphasis added.]

Applicant's construal of the claim language for claim 48 to require distinction between structural elements and sensor elements is also corroborated and supported by the originally filed application on page 24, lines 9-22, wherein Applicant describes the endothelialization biosensor embodiment (illustrated in Figs. 9-10 and defined in dependent claim 55, which indirectly depends from independent claim 48) in which the structural elements (*i.e.*, wall elements 42) are distinct from sensor elements 50:

> The binding regions 50 are similar to the sensor regions of the above-described embodiments, except the binding regions 50 comprise regions of the implantable substrate carrier 42 which have biochemical markers, such as antibodies or ligands, bound thereto which are specific for endothelial and/or smooth muscle cell surface proteins or precursors of endothelial cell and smooth cell proliferation, such as vascular endothelial growth factor or other growth factors. The material of the implantable substrate carrier 42 is preferably fabricated of a shape memory or superelastic material, which, upon binding of biological material to the biochemical markers in the binding regions 50, undergoes phase transformation due either the binding to the biochemical markers alone or in combination with an applied energy to the bound complex. The phase transformation of the material to the implantable substrate carrier will cause a frequency shift in a returned signal from the applied energy source and will be indicative of the bound state of the binding domain 50. [Emphasis added.]

The claimed invention's sensor elements (20, 22, and 50) are clearly illustrated in Figs. 1-4 and 8-10. While Applicant acknowledges that sensor elements are not explicitly shown in Figs. 5-7, those skilled in the art reading the above-recited passages would readily understand that the embodiment illustrated in Figs. 5-7 inherently incorporates sensor elements.

Furthermore, Applicant notes that, contrary to the Examiner's assertion, the claimed invention, as defined by claims 48-49 and 51-66, is not limited to the Vascular Imaging Sensor embodiment illustrated in Figs. 5-7. Applicant submits that the invention defined by claim 48 is a generic claim that encompasses several embodiments (if not all embodiments) described in the pending application. For instance, claim 58 recites, *inter alia*, "cellular binding and molecular binding," which corresponds to the Endothelialization Biosensor Embodiment illustrated in Figs. 8-10. Applicant respectfully submits that the Examiner's narrow view of claim 48 to encompass only the Vascular Imaging Sensor embodiment illustrated in Figs. 5-7 is misplaced.

> On page 5, lines 12-15 of the Examiner's Answer the Examiner further argues:
>
> The examiner disagrees with that the applicant has not claimed that the sensors are limited to only a portion of the stent. Further, the first sensor of Burmeister (either some of the strands 12 or a layer 32 of all strands or some of the strands; is only a portion of the stent, because it does not include strands 14 or layer 34).

Applicant is confused as to what the Examiner is trying to convey in the above passage. Nonetheless, in response to the Examiner's arguments above, Applicant submits (for the reasons described above) that claim 48, as currently written, requires the sensor elements to be distinct from the structural elements. Thus, as currently written, claim 48 requires that the sensor elements combined not form the entire stent structure itself.

> On page 5, lines 16-21 of the Examiner's Answer the Examiner further argues:
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> The applicant argues that Burmeister does not disclose laminates. The examiner disagrees. Figure 3 clearly showed a layer structure (laminate), further disclosing that such layered laminate shown in figure 3 may be applied to any stent configuration, such as those shown in figures 1, 5-10, etc, see col.6, lines 20-26, thus all structural elements such as 12 and 14 of figure 1 would have such a layered structure; and may further have additional layers than those shown in figure 3, col. 6, lines 32-36. [Emphasis added.]

In the above-recited passage, **the Examiner utterly distorts and mischaracterizes** what Applicant actually suggested in the Appeal Brief. Applicant **never** argued that Burmeister did not disclose laminates. Rather, Applicant noted that "the terms 'laminated' and 'structural elements' do not exist anywhere in Burmeister." (*See*, Appeal Brief, page 6, lines 14-15.) Applicant sought clarity as to what structures described in Burmeister the Examiner interpreted as corresponding to the terms "structural elements" and "laminated". Moreover, Applicant

specifically noted in the Appeal Brief that "[w]hile Burmeister does disclose an embodiment (as illustrated in Figure 3) that **may be considered to have two layers laminated to each other**, the embodiment referenced by the Examiner (as illustrated in Figure 1) to form the basis for his anticipation rejection does not have laminated layers." (*See*, Appeal Brief, page 7, lines 4-7.) Indisputably, Applicant has already acknowledged that the embodiment illustrated in Fig. 3 of Burmeister may constitute lamination. However, the Examiner did not show (and still has not shown) how the embodiment illustrated in Fig. 3 can be modified and applied to other embodiments in Burmeister to arrive at the claimed invention.

To conclude, Applicant submits that the claims, the specification, and the drawings, clearly establish that the invention defined by claim 48 requires that sensor elements be considered distinct from structural elements. Burmeister does not teach this feature because Burmeister teaches a stent that is composed entirely of only two structural elements. Burmeister fails to teach a stent that comprises four distinct elements: a first structural element, a first sensor element, a second structural element, and a second sensor element. Accordingly, Applicant submits that the Examiner's anticipation rejection is improper and should be withdrawn.

B. The strands described in the two-component Burmeister stent do not qualify as a sensor.

Applicant notes again that Burmeister never references the term "sensor" nor any other term that may be considered analogous in meaning to the term "sensor". Nonetheless, on page 6, lines 3-8 of the Examiner's Answer, the Examiner maintains her position and states her reasons as to why she believes Burmeister teaches a sensor:

> Burmeister clearly discloses a stent with elements (struts/strands 12, 14 for example) that are responsive to changes in temperature and pressure, thus act as a sensor and may be considered a sensor since the elements (or portions of the elements) perform the function of **sensing** stimuli. Burmeister's stent is exactly configured the same as applicants [sic] stent seen in elected figures 5-7B, having struts/strands (structural elements) that are shape memory or superelastic materials and respond to changes in temperature or pressure.

Applicant readily acknowledges that Burmeister's stent would respond to changes in temperature and pressure. However, just because an object responds to pressure or temperature does not automatically qualify that object to be a "sensor", as the term "sensor" is understood by those

skilled in the art. Human beings respond to changes in temperature and pressure. A person subjected to high temperatures will respond by sweating. Conversely, a person subjected to low temperatures will respond by shivering. However, those skilled in the art would not define a human being as a sensor. The Examiner's unconventional interpretation of the term "sensor" goes against the meaning recognized by those in the art.

On page 6, lines 8-12 of the Examiner's Answer, the Examiner further argues:

> Because applicant is terming the structural member having such a response a "sensor", Burmeister's may also be considered as "sensor" since it is the same as applicants [sic]. Applicant's "sensor" is simply a shape memory or superelastic material. Burmeister discloses such materials thus inherently by evidence of applicants [sic] specification, have a "sensor", since shape memory and superelastic materials are sensors.

Applicant respectfully disagrees with the Examiner's view. Contrary to the Examiner's assertion, just because Burmeister discloses use of a shape memory material does not imply that Burmeister teaches a sensor. Under the Examiner's illogical reasoning, any object formed of shape memory or superelastic material would qualify as a sensor. This type of interpretation is illogical and runs counter to what is accepted by those skilled in the art. As noted previously, Applicant's stent is formed of at least four elements: a first structural element, a first sensor element, a second structural element, and a second sensor element.[1] The sensor elements are specifically configured and designed to be formed of shape memory materials that are different from the shape memory materials used to form the sensor elements. It is this specific configuration, not the use of shape memory material itself, that makes Applicant's stent a sensor.

On page 6, lines 13-18 of the Examiner's Answer, the Examiner further argues:

> Further, applicant has cited a definition of sensor to be "a device that responds to a physical stimulus and transmits a resulting response". Burmeister's stent clearly responds to a physical stimulus (heat, when placing the device from an outside environment to inside a persons [sic] body, or when a person has a fever, increase in temperature, or application of pressure, such as a balloon catheter, all are physical stimulus disclosed by Burmeister) and transmits a resulting response (Burmeister's response is a change in conformation of the stent, expansion.)

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[1] Page 23, lines 22-26 of the originally filed application describes: "Alternatively, portions of the wall elements 32, 36 may be fabricated of a first material having a transition point T_1, while other portions of the wall elements 32, 36 ... are fabricated of second material having a transition point T_2."

Applicant acknowledges that Burmeister's stent is capable of responding to physical stimulus, just as an ice cube (which is not commonly associated as a sensor) would respond to temperature changes by either melting or expanding. Whether Burmeister's stent responds to stimulus is not the issue. The real issue is whether Burmeister describes a stent with a configuration that is identical to Applicant's, *i.e.*, a configuration having at least four distinct elements: a first structural element, a first sensor element, a second structural element, and a second sensor element. For reasons described above, Burmeister fails to describe a stent with Applicant's configuration.

Moreover, Applicant notes that the Burmeister stent is not even designed to function as a sensor. Instead, it is designed for use "in a multiple component arrangement which allows for initial self-expansion and subsequent deformation to a final enlarged diameter in the body." [Emphasis added.] (*See*, Burmeister, paragraph 6.) Furthermore, the purpose of this specific design is to "control the degree of expansion [of the stent] and hence the degree of embedment in the vessel wall." [Emphasis added] (*See*, Burmeister, paragraph 8). In other words, after implantation, the Burmeister stent is designed to enter into a passive state, whereby the stent's physical properties theoretically remain constant and are not intended to react/respond to internal conditions of the body, let alone react/respond to an externally applied energy/stimulus, as recited in pending claim 48. Thus, after implantation and initial expansion, the Burmeister stent is not designed to undergo any additional conformational changes within the device. Accordingly, the Burmeister stent can not function, and is not even intended to function, as a sensor in the manner suggested by the Examiner, *i.e.*, by stimulating the stent with energy to induce conformational changes.

Furthermore, as noted in the Appeal Brief and as acknowledged by the Examiner, a sensor is widely accepted as a "device that responds to a physical stimulus (such as heat, light, pressure, magnetism, or a particular motion) and transmits a resulting response (as for measurement or operating a control)." [Emphasis added.][2] In the Examiner's Answer, the Examiner fails to point out to a teaching or suggestion in Burmeister for "transmitting" a response. Based on Applicant's meticulous reading of Burmeister, Applicant submits that Burmeister does not teach a stent that "transmits" a response. Accordingly, Burmeister's stent does not qualify as a "sensor", as the term "sensor" is understood by those skilled in the art.

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[2] *See*, Webster's Online Dictionary <http://www.m-w.com>.

In contrast, the application as filed clearly describes in detail how the claimed invention's sensor element transmits responses. On page 21, lines 9-13, Applicants describes:

> The returned signal may be generated by a passive transmitter embedded in solid state circuitry defined within the sensor 20, wherein the cantilever members 20 serve as electromechanical switches which alter a property of the solid state circuitry, for example, impedance or capacitance, and which then returns a detectable signal representative of the number and positions of cantilever member 22 in the "on" position. [Emphasis added.]

To conclude, Burmeister's stent does not constitute a sensor because it: (1) does not transmit a response; and (2) is not designed, configured, or intended to function as a sensor. Because Burmeister fails to teach a sensor that corresponds to the sensor element recited in claims 48-49 and 51-66, Applicant submits that the Examiner's anticipation rejection is improper and should be withdrawn.

C. Burmeister does not Enable the Claimed Invention

On page 11, line 9 – page 12, line 30 of the Appeal Brief, Applicant submitted arguments explaining why Burmeister's disclosure does not enable one skilled in the art to arrive at the claimed invention. In response, the Examiner argues: "The applicant has further argued that Burmeister does not enable the claimed invention. The examiner disagrees for all the above reasons." Applicant is confounded by the Examiner's response, given that she provides no explanation as to why she believes Burmeister enables one skilled in the art to arrive at the claimed invention. Applicant notes that the standard for enablement is distinct from the standard for anticipation. While the Examiner has submitted reasons explaining why she believes that Burmeister anticipates the claimed invention, the Examiner has submitted no reason explaining why Burmeister would enable one skilled in the art to arrive at the claimed invention. Applicant submits that the enablement (or lack thereof) issue is quite relevant, especially given that Burmeister makes absolutely no mention of the term "sensor" or any other term with an equivalent meaning. Applicant further submits that by not describing how its stent would operatively function as a sensor, Burmeister cannot serve as an enabling disclosure with respect to anticipating a stent having sensor elements, as recited in the pending claims.

Conclusion

An anticipation rejection under 35 U.S.C. §102(b) requires that there be identity between the claimed elements and the cited prior art references. Such identity is unequivocally absent between the elements of the rejected claims and the Burmeister reference. In the absence of such identity, Applicant respectfully solicits the Board to reverse the Examiner's rejections and allow claims 48-49 and 51-66.

Respectfully submitted,

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